

11-01-04

Attorney's Docket No.: 13681-012001

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Otterbein et al.

Art Unit : 1614

Serial No. : 10/600,182

Examiner : Unknown

Filed : June 20, 2003

Title : PHARMACEUTICAL USE OF NITRIC OXIDE, HEME OXYGENASE-1 AND
PRODUCTS OF HEME DEGRADATION

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants submit copies of the references listed on the attached form PTO-1449. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

Applicants wish to bring to the Examiner's attention the following Non-Provisional applications, all of which have overlapping inventorship with the above-referenced application:

<u>Serial No.</u>	<u>Applicants</u>	<u>Filed</u>	<u>Status</u>
09/538,788	Choi et al.	3/30/00	Abandoned
10/177,930	Bach et al.	6/21/02	Pending
10/053,535	Choi et al.	1/15/02	Pending
10/367,277	Otterbein et al.	2/13/03	Pending
10/371,666	Otterbein et al.	2/21/03	Pending
10/413,817	Otterbein et al.	4/15/03	Pending
10/439,632	Otterbein et al.	5/16/03	Pending
10/455,564	Otterbein et al.	6/05/03	Pending
10/676,280	Billiar et al.	9/30/03	Pending

This statement is being filed before the receipt of a first Office action on the merits.

CERTIFICATE OF MAILING BY EXPRESS MAIL

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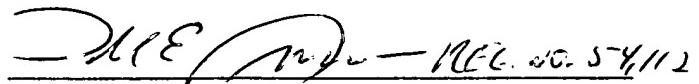
Applicant : Otterbein et al.
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Filed : June 20, 2003
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Attorney's Docket No.: 13681-012001

Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 13681-012001.

Respectfully submitted,

Date: 10/29/04


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Substitute Form PTO-1449
(Modified)U.S. Department of Commerce
Patent and Trademark OfficeAttorney's Docket No.
13681-012001Application No.
10/600,182

**Information Disclosure Statement
by Applicant**
(Use several sheets if necessary)

(37 CFR §1.98(b))

Applicant
Otterbein et al.Filing Date
June 20, 2003Group Art Unit
1614**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	4,053,590	10/11/77	Bonsen et al.			
	AB	4,264,739	4/28/81	Grabner et al.			
	AC	4,923,817	5/8/90	Mundt			
	AD	5,180,366	01/19/93	Woods			
	AE	5,240,912	8/31/93	Todaro			
	AF	5,449,665	09/12/95	Sollevi			
	AG	5,476,764	12/19/95	Bitensky			
	AH	5,763,431	06/9/98	Jackson			
	AI	5,792,325	08/11/98	Richardson, Jr.			
	AJ	5,882,674	03/16/99	Herrmann et al.			
	AK	5,885,621	3/23/99	Head et al.			
	AL	6,066,333	05/23/00	Willis et al.			
	AM	6,313,144	11/6/01	McCullough et al.			
	AN	6,316,403	11/13/01	Pinsky et al.			
	AO	200300664114	04/03/03	Motterlini et al.			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AP	JP 56079957A	06/30/81	Japan			English Abstract by Derwent Information Ltd	
	AQ	WO 95/35105	12/28/95	WIPO				
	AR	WO 98/08523	03/05/98	WIPO			X	
	AS	WO 02/09731	02/07/02	WIPO			English Abstract	
	AT	WO 03/000114	01/03/03	WIPO				
	AU							

Other Documents (include Author, Title, Date, and Place of Publication)

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Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 13681-012001	Application No. 10/600,182
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Otterbein et al.		
		Filing Date June 20, 2003	Group Art Unit 1614	

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	AU	Abidin <i>et al.</i> , "The Combined Effect of Carbon Monoxide and Normobaric Hyperoxia on Animals", <i>Kosmicheskaya Biologiya I Aviakosmicheskaya Meditsina</i> 6: 63-67 (1978)
	AV	Arita <i>et al.</i> , "Prevention of Primary Islet Isograft Nonfunction in Mice with Pravastatin," <i>Transplantation</i> 65:1429-33 (1998)
	AW	Arnush <i>et al.</i> , "IL-1 Produced and Released Endogenously within Human Islets Inhibits β Cell Function," <i>J. Clin Invest.</i> 102:516-26 (1998)
	AX	Bach <i>et al.</i> , "Accommodation of vascularized xenografts: Expression of "protective genes" by donor endothelial cells in a host Th2 cytokine environment," <i>Nature Med.</i> 3:196-204 (1997)
	AY	Berney <i>et al.</i> , "Islet cell transplantation: the future?" <i>Langenbeck's Arch. Surg.</i> 385: 373-8 (2000)
	AZ	Bentley <i>et al.</i> , "Successful Cardiac Transplantation with Methanol or Carbon Monoxide-Poisoned Donors," <i>Thorac Surg</i> 71(4):1194-7 (2001)
	AAA	Brouard <i>et al.</i> , "Carbon Monoxide Generated by Heme Oxygenase-1 Suppresses Endothelial Cell Apoptosis," <i>J Exp Med</i> 192(7):1015-25 (2000)
	ABB	Brown <i>et al.</i> , "In vivo binding of carbon monoxide to cytochrome c oxidase in rat brain", American Physiological Society, pp 604-610 (1990)
	ACC	Campbell, "Living At Very High Altitudes", <i>The Lancet</i> 1:370-373 (1930)
	ADD	Campbell, "The Effect of Carbon Monoxide and Other Agents Upon the Rate of Tumour Growth", <i>J Pathology & Bacteriology</i> 35:379-394 (1932)
	AEE	Campbell, "Cancer of Skin and Increase in Incidence of Primary Tumours of Lung in Mice Exposed to Dust Obtained from Tarred Roads", <i>Brit. J Exper. Pathol.</i> XV(5):24, 289-294 (1934)
	AFF	Cantrell <i>et al.</i> , "Low-Dose Carbon Monoxide Does Not Reduce Vasoconstriction in Isolated Rat Lungs", <i>Experimental Lung Research</i> 22:21-32 (1996)
	AGG	Cardell <i>et al.</i> , "Bronchondilatation <i>in vivo</i> by carbon monoxide, a cyclic GMP related messenger", <i>British J. of Pharmacology</i> 124:1065-1068 (1998)
	AHH	Carlsson <i>et al.</i> , "Measurements of Oxygen Tension in Native and Transplanted Rat Pancreatic Islets," <i>Diabetes</i> 47:1027-32 (1998)
	AII	Carraway <i>et al.</i> , "Induction of ferritin and heme oxygenase-1 by endotoxin in the lung", <i>Am J Physiol Lung Cell Mol Physiol</i> 275:L583-592 (1998)
	AJJ	Cecil Textbook of Medicine (21 st Ed. 2000) 1:273-279, 357-372, 387-419, 425-427, 436-448, 466-475, 507-512, 1060-1074
	AKK	Cecil Textbook of Medicine (21 st Ed. 2000) 2:1492-1499, 2042-2047, 2079-2081
	ALL	Chapman <i>et al.</i> , "Exogenous Carbon Monoxide Attenuates Aeroallergen-induced Eosinophilic Inflammation in Mice", <i>J Respiratory Critical Care Med</i> 159(3):A218 (1999)
	AMM	Chapman <i>et al.</i> , "Carbon Monoxide Attenuates Aeroallergen-induced Inflammation in Mice", <i>Am. J. Physiol. Lung Cell Mol Physiol.</i> 281:L209-L216 (2001)
	ANN	Choi <i>et al.</i> , "Heme Oxygenase-1: Function, Regulation, and Implication of a Novel Stress-inducible Protein in Oxidant-induced Lung Injury", <i>Am. J. Respir. Cell Mol. Biol.</i> 15:9-19 (1996)
	AOO	Christodoulides <i>et al.</i> , "Vascular Smooth Muscle Cell Heme Oxygenases Generate Guanylyl Cyclase-Stimulatory Carbon Monoxide," <i>Circulation</i> 97:2306-9 (1995)
	APP	Corbett <i>et al.</i> , "Nitric oxide mediates cytokine-induced inhibition of insulin secretion by human islets of Langerhans," <i>Proc. Natl. Acad. Sci USA</i> 90:1731-5 (1993)
	AQQ	Davidson <i>et al.</i> , "Inflammatory Modulation and Wound Repair" <i>J Investigative Dermatology</i> xi-xii (2003)

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Other Documents (include Author, Title, Date, and Place of Publication)

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	ARR	Dioum <i>et al.</i> , "NPAS2: A Gas-Responsive Transcription Factor", <i>Scienceexpress/www.scienceexpress.org/21 November 2002/pages 1-6/10.1126/science.1078456</i>
	ASS	Donnelly <i>et al.</i> , "Expression of Heme-Oxygenase in Human Airway Primary Epithelial Cells", <i>J Respiratory Critical Care Med</i> 159(3):A218 (1999)
	ATT	Friebe <i>et al.</i> , "YC-1 Potentiates Nitric Oxide- and Carbon Monoxide-Induced Cyclic GMP Effects in Human Platelets", <i>Molecular Pharmacology</i> 54: 962-967 (1998)
	AUU	Gaine <i>et al.</i> , "Induction of Heme Oxygenase-1 with Hemoglobin Depresses Vasoreactivity in Rat Aorta," <i>J Vasc Res</i> 36(2):114-9 (1999)
	AVV	Grau <i>et al.</i> , "Influence of Carboxyhemoglobin Level on Tumor Growth, Blood Flow, and Radiation Response in an Experimental Model," <i>Int. J. Radiation Oncology Biol. Phys.</i> 22:421-424 (1992)
	AWW	Grau <i>et al.</i> , "Effect of Carbon Monoxide Breathing on Hypoxia and Radiation Response in the SCCVII Tumor <i>in vivo</i> ", <i>Int. J. Radiation Oncology Biol. Phys.</i> 29:449-454 (1994)
	AXX	Hantson <i>et al.</i> , "Organ Transplantation From Victims of Carbon Monoxide Poisoning," <i>Ann Emerg Med</i> 27(5):673-4 (1996)
	AYY	Hebert <i>et al.</i> , "Transplantation of Kidneys from a Donor with Carbon Monoxide Poisoning," <i>New Engl J Med</i> 326(23):1571 (1992)
	AZZ	Iberer <i>et al.</i> , "Cardiac Allograft Harvesting after Carbon Monoxide Poisoning. Report of a Successful Orthotopic Heart Transplantation," <i>J Heart Lung Transplant</i> 12(3):499-500 (1993)
	AAAA	Katori <i>et al.</i> , "Heme Oxygenase-1 System in Organ Transplantation", <i>Transplantation</i> 74(7):905-912 (2002)
	ABBB	Kaufman <i>et al.</i> , "Differential Roles of Mac-1 ⁺ Cells, and CD4 ⁺ and CD8 ⁺ T Lymphocytes in Primary Nonfunction and Classic Rejection of Islet Allografts," <i>J Exp Med.</i> 172:291-302 (1990)
	ACCC	Koerner <i>et al.</i> , "Extended Donor Criteria: Use of Cardiac Allografts after Carbon Monoxide Poisoning," <i>Transplantation</i> 63(9):1358-60 (1997)
	ADDD	Lacy <i>et al.</i> , "Transplantation of Pancreatic Islets," <i>Ann. Rev. Immunol.</i> 2:183-98 (1984)
	AEEE	Lee <i>et al.</i> , "Regulation of Heme Oxygenase-1 Expression <i>In Vivo</i> and <i>In Vitro</i> in Hyperoxic Lung Injury", <i>Am. J. Respir. Cell Biol.</i> 14:556-568 (1996)
	AFFF	Lefer <i>et al.</i> , "A Comparison of Vascular Biological Actions of Carbon Monoxide and Nitric Oxide", <i>Meth Find Exp Clin Pharmacol</i> 15(9):617-622 (1993)
	AGGG	Leikin <i>et al.</i> , "The Toxic Patient as a Potential Organ Donor," <i>Am J Emerg Med</i> 12(2):151-4 (1994)
	AHHH	Mandrup-Poulsen <i>et al.</i> , "Human Tumor Necrosis Factor Potentiates Human Interleukin 1-Mediated Rat Pancreatic β -Cell Cytotoxicity," <i>J. Immunol</i> 139:4077-82 (1987)
	AIII	Mansouri <i>et al.</i> , "Alteration of Platelet Aggregation by Cigarette Smoke and Carbon Monoxide," <i>Thromb Haemost</i> 48:286-8 (1982)
	AJJJ	Maxwell <i>et al.</i> , "Studies in Cancer Chemotherapy: XI. The Effect of CO, HCN, and Pituitrin Upon Tumor Growth", Dept. of Cancer Research , Santa Barbara Cottage Hospital, pp 270-282 (Jan. 30, 1933)
	AKKK	Meilin <i>et al.</i> , Effects of carbon monoxide on the brain may be mediated by nitric oxide", <i>J Appl Physiol.</i> 81(3):1078-83 (1996)
	ALLL	The Merck Manual (16 th Ed. 1992) pp. 646-657
	AMMM	Minamino <i>et al.</i> , "Targeted expression of heme oxygenase-1 prevents the pulmonary inflammatory and vascular responses to hypoxia", <i>PNAS</i> 98(15):8798-8803 (2001)

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	ANNN	Myers, "Cirrhotic cardiomyopathy and liver transplantation," <i>Liver Transpl</i> 6(4 Suppl 1):S44-52 (2000)
	AOOO	Nagata et al., "Destruction of Islet Isografts by Severe Nonspecific Inflammation," <i>Transplant Proc.</i> 22:855-6 (1990)
	APPP	The New Encyclopedia Britannica (15 th ed. 1994) Vol. 26, <i>Macropaedia</i> , p. 756
	AQQQ	Otterbein et al., "Mechanism of hemoglobin-induced protection against endotoxemia in rats: a ferritin-independent pathway", <i>Am J Physiol Lung Cell Mol Physiol</i> 272:L268-275 (1997)
	ARRR	Otterbein et al., "Carbon monoxide has anti-inflammatory effects involving the mitogen-activated protein kinase pathway", <i>Nature Medicine</i> 6(4): 422-8 (2000)
	ASSS	Otterbein et al., "Carbon monoxide provides protection against hyperoxic lung injury", <i>The American Physiological Society</i> L688-L694 (1999)
	ATTT	Otterbein et al., "Carbon monoxide provides protection against hyperoxic lung injury in rats", <i>J Respiratory Critical Care Med</i> 159(3):A218 (1999)
	AUUU	Paredi et al., "Increased Carbon Monoxide in Exhaled Air of Cystic Fibrosis Patients", <i>J Respiratory Critical Care Med</i> 159(3):A218 (1999)
	AVVV	Petrache et al., "Heme oxygenase-1 inhibits TNF- α -induced apoptosis in cultured fibroblasts," <i>Am. J. Physiol. Lung Cell Mol. Physiol.</i> 287: L312-L319 (2000).
	AWWW	Piantadosi et al., "Production of Hydroxyl Radical in the Hippocampus After CO Hypoxia Hypoxia in the Rat", <i>Free Radical Biol. & Med.</i> 22(4):725-732 (1997)
	AXXX	Pozzoli et al., "Carbon Monoxide as a Novel Neuroendocrine Modulator: Inhibition of Stimulated Corticotropin-Releasing Hormone Release from Acute Rat Hypothalamic Explants," <i>Endocrinology</i> 135:2314-2317 (1994)
	AYYY	Rabinovitch et al., "Transfection of Human Pancreatic Islets With an Anti-Apoptotic Gene (<i>bcl-2</i>) Protects β -Cells From Cytokine-Induced Destruction," <i>Diabetes</i> 48:1223-9, 1999
	AZZZ	Ringel et al., "Carbon Monoxide-induced Parkinsonism", <i>J. neurol. Sci.</i> 16:245-251 (1972)
	AAAAAA	Roberts et al., "Successful Heart Transplantation From a Victim of Carbon Monoxide Poisoning," <i>Ann Emerg Med</i> 26(5):652-5 (1995)
	ABBBB	Sato et al., "Carbon Monoxide Generated by Heme Oxygenase-1 Suppresses the Rejection of Mouse-to-Rat Cardiac Transplants," <i>J. Immunol.</i> 166: 4185-4194 (2001)
	ACCCC	Schipper et al., "Expression of Heme Oxygenase-1 in the Senescent and Alzheimer-diseased Brain", <i>Annals of Neurology</i> 37(6): 758-68 (1995)
	ADDDD	Shapiro et al., "Islet Transplantation in Seven Patients with Type 1 Diabetes Mellitus Using a Glucocorticoid-Free Immunosuppressive Regimen," <i>N Engl. J. Med.</i> , 343:230-8, 2000
	AEEEE	Shennib et al., "Successful transplantation of a lung allograft from a carbon monoxide-poisoning victim," <i>Heart Lung Transplant</i> 11(1 Pt 1): 68-71 (1992)
	AFFFF	Singhal et al., "Effects of Normobaric Hyperoxia in a Rat Model of Focal Cerebral Ischemia-Reperfusion", <i>J Cerebral Blood Flow & Medicine</i> 22:861-868 (2002)
	AGGGG	Siow et al., "Heme oxygenase-carbon monoxide signalling pathway in atherosclerosis: anti-atherogenic actions of bilirubin and carbon monoxide?", <i>Cardiovascular Research</i> 41:385-394 (1999)
	AHHHH	Smith et al., "Successful Heart Transplantation with Cardiac Allografts Exposed to Carbon Monoxide Poisoning," <i>Heart Lung Transplant</i> 11(4 Pt. 1):698-700 (1992)

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	AIIII	Soares <i>et al.</i> , "Expression of heme oxygenase-1 can determine cardiac xenograft survival," <i>Nat Med.</i> 4(9):1073-1077 (1998)
	AJJJJ	Stephens <i>et al.</i> , "Further Observations Regarding Carbon Monoxide Gas as an Important Factor in the Causation of Industrial Cancer", <i>Medical Press and Circular</i> 183:283-288 (1933)
	AKKKK	Tamayo <i>et al.</i> , "Carbon monoxide inhibits hypoxic pulmonary vasoconstriction in rats by a cGMP-independent mechanism", <i>Pflugers Arch.</i> 434(6):698-704 (1997)
	ALLLL	Taylor, "Anti-TNF Therapy for Rheumatoid Arthritis and Other Inflammatory Diseases", <i>Molecular Biotechnology</i> 19:153-168 (2001)
	AMMMM	Tenderich <i>et al.</i> , "Hemodynamic follow-up of cardiac allografts from poisoned donors," <i>Transplantation</i> 66(9):1163-7 (1998)
	ANNNN	Tenhuunen <i>et al.</i> , "The Enzymatic Conversion of Heme to Bilirubin by Microsomal Heme Oxygenase," <i>Proc Natl Acad Sci USA</i> 61:748-755 (1968)
	AOOOO	Tulis <i>et al.</i> , "Adenovirus-Mediated Heme Oxygenase-1 Gene Delivery Inhibits Injury-Induced Vascular Neointima Formation", <i>Circulation</i> 104:2710-2715 (2001)
	APPPP	Utz <i>et al.</i> , "Carbon Monoxide Relaxes Ileal Smooth Muscle Through Activation of Guanylate Cyclase," <i>Biochem Pharmacol.</i> 47:1195-201, 1991
	AQQQQ	Vassalli <i>et al.</i> , "Inhibition of Hypoxic Pulmonary Vasoconstriction By Carbon Monoxide in Dogs", European Respiratory Journal, ERS Annual Congress, Geneva, Switzerland, Sept 19-23 (1998)
	ARRRR	Verma <i>et al.</i> , "Carbon Monoxide: A Putative Neural Messenger," <i>Science</i> 259:381-384, 1993
	ASSSS	Verran <i>et al.</i> , "Use of Liver Allografts from Carbon Monoxide Poisoned Cadaveric Donors," <i>Transplantation</i> 62(10):1514-5 (1996)
	ATTTT	Wang <i>et al.</i> , "Resurgence of carbon monoxide: an endogenous gaseous vasorelaxing factor", <i>Can. J. Physiol. Pharmacol.</i> 76:1-15 (1998)
	AUUUU	Weir <i>et al.</i> , "Scientific and Political Impediments to Successful Islet Transplantation," <i>Diabetes</i> 46:1247-56, 1997
	AVVVV	Weir <i>et al.</i> , "Islet transplantation as a treatment for diabetes," <i>J. Am. Optom. Assoc.</i> 69:727-32, 2000
	AWWWW	Welty <i>et al.</i> , "Hyperoxic Lung Injury is Potentiated by SPC-Promotor Driven Expression of an HO-1 Transgene in Mice", <i>J Respiratory Critical Care Med</i> 159(3):A218 (1999)
	AXXXX	Weng <i>et al.</i> , "Transpulmonary HO-1 Gene Delivery in Neonatal Mice", <i>J Respiratory Critical Care Med</i> 159(3):A218 (1999)
	AYYYY	Yuan <i>et al.</i> , "Evidence of increased endogenous carbon monoxide production in newborn rat endotoxicosis," <i>Chinese Medical Sciences Journal</i> (1997), Vol. 12, No. 4, 212-215.

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